

as shortened by any terminal disclaimer;

(3) By adding 14 years to the date of the issuance of a license under the Virus-Serum-Toxin Act;

(4) By comparing the dates for the ends of the periods obtained pursuant to paragraphs (d)(2) and (d)(3) of this section with each other and selecting the earlier date;

(5) If the original patent was issued after November 16, 1988, by—

(i) Adding 5 years to the original expiration date of the patent or any earlier date set by terminal disclaimer; and

(ii) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(5)(i) of this section with each other and selecting the earlier date;

(6) If the original patent was issued before November 16, 1988, and

(i) If no request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, by—

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, and the commercial marketing or use of the product was not approved before November 16, 1988, by—

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30382, July 20, 1989]

§ 1.780 Certificate of extension of patent term.

If a determination is made pursuant to § 1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or certificate of interim extension under 35 U.S.C.

156(d)(5) will be issued to the applicant for the extension of the patent term. Such certificate will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate of extension will be published in the Official Gazette of the Patent and Trademark Office. Notification of the issuance of the certificate of interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the Official Gazette of the Patent and Trademark Office and in the FEDERAL REGISTER. No certificate of extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations the final determination made pursuant to § 1.750 will indicate that no certificate will issue.

[60 FR 25618, May 12, 1995]

§ 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.

(a) Only one patent may be extended for a regulatory review period for any product (§ 1.720(h)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the patents are otherwise eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for